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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
KELLY, ROBERT M	

ART UNIT	PAPER NUMBER
1633	

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02/18/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/572,732	ZINN ET AL.	
	Examiner	Art Unit	
	ROBERT M. KELLY	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 November 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-165* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-165* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendment and response to restriction of 11/20/08 are entered.

Claims 152-165 are newly added.

Claims 1-165 are presently pending.

In light of further consideration, the restriction requirement is withdrawn in favor of the following new restriction requirement:

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-39, drawn to a method of detecting inflammation in a subject.

Group II, claim(s) 40-67, drawn to a method of detecting inflammation in a transplant, post transplantation.

Group III, claim(s) 68-91, drawn to a method of monitoring inflammation in a subject with inflammatory or autoimmune disease.

Group IV, claim(s) 92-105, drawn to a method of identifying a vector capable of detecting inflammation.

Group V, claim(s) 106-123, drawn to a method of treating inflammatory disease, comprising detection of an expressed nucleic acid and modifying treatment upon detection.

Group VI, claim(s) 124-127 and 165, drawn to treating inflammation in a subject by administration of a complement modulator.

Group VII, claim(s) 124-124, 130-132, 134, and 152-165, drawn to treating inflammation in a subject by administration of a nucleic acid encoding a complement modulator.

Group VIII, claim(s) 128, drawn to a transgenic animal.

Group IX, claim(s) 129, drawn to a cell line comprising a vector with a reporter nucleic which is expressed under conditions of inflammation.

Group X, claim(s) 133, 135, 136, 142-145, 150, and 151, drawn to a nucleic acid encoding at least two repeats of ED1 and a linker.

Group XI, claim(s) 137-141, 146, and 147-149, drawn to a nucleic acid encoding SEQ ID NO: 8 with at least 80% identity.

The inventions listed as Groups I-XI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the special technical feature between any two specific inventions appears to be the promoter-reporter or a substance which treats inflammation. U.S. Patent No. 5,744,304 claims inflammation-responsive promoters linked to transgenes and delivered to subjects. Further, the specification teaches the use of reporter nucleic acids as the transgene (EXAMPLES), and some claims are drawn to therapeutic nucleic acids. Such necessarily teaches all aspects of the special technical feature(s) shared between any two inventions. Moreover, each invention contains specific structures (e.g., group IX requires two repeats of ED1 and a linker) or specific steps (e.g., Group II requires transforming transplant tissue) which are not common to other inventions, and hence require distinct structural and functional considerations such that the Artisan would not necessarily find the art and cover the considerations for any two inventions together. Hence, the inventions do not share the same general inventive concept. Moreover, such distinct searches would pose a serious burden on the Examiner to search and consider any two inventions together.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

If Applicant should choose invention I:

Applicant is required to choose a single promoter from the group consisting of Cox2L, Cox2M (as in Claim 3), or a specific promoter specifically supported in the specification.

Applicant is required to choose a single reporter from the group consisting of luciferase, GFP, RFP, hSSr2, TK, SEAP (as in Claims 5-9, 11, and 37), or a specific reporter specifically supported in the specification.

Applicant is required to choose a single specific cause of inflammation, chosen from those of Claims 20-23, 30, or 32, or such other specific cause of inflammation supported by the specification. **For this, it is noted that many things are noted as "associated" with something else. The Examiner is requiring the specific cause, and not some broad association. Failure to choose something specific to a specific thing (e.g., associated with cancer is a genera, encompassing the cancer, as well various side-effects of treatments) will yield a non-responsive notice.**

Applicant is required to choose a single specific complement inhibitor, chosen from the group consisting of SCR 13-15, Crry (as in Claims 14-15), and a specific complement inhibitor specifically supported by the specification.

If Applicant should choose invention II:

Applicant is required to choose a single promoter from the group consisting of Cox2L, Cox2M (as in Claim 49), or a specific promoter specifically supported in the specification.

Applicant is required to choose a single reporter from the group consisting of luciferase, GFP, RFP, hSSr2, TK, SEAP (as in Claims 52-55, 57, and 66), or a specific reporter specifically supported in the specification.

Applicant is required to choose a single specific cause of inflammation, chosen from those of Claims 59 and 63, or such other specific cause of inflammation supported by the specification. **For this, it is noted that many things are noted as "associated" with**

something else. The Examiner is requiring the specific cause, and not some broad association. Failure to choose something specific to a specific thing (e.g., "associated with cancer" is a genera, encompassing the cancer, as well various side-effects of treatments) will yield a non-responsive notice.

Applicant is required to choose a single specific complement inhibitor, chosen from the group consisting of SCR 13-15, Crry, (as in Claims 47-48) and a specific complement inhibitor specifically supported by the specification.

If Applicant should choose invention III:

Applicant is required to choose a single promoter from the group consisting of Cox2L, Cox2M (as in Claim 74), or a specific promoter specifically supported in the specification.

Applicant is required to choose a single reporter from the group consisting of luciferase, GFP, RFP, hSSr2, TK, SEAP (as in Claims 76, 78-80, 82, and 90), or a specific reporter specifically supported in the specification.

Applicant is required to choose a single specific cause of inflammation, chosen from those of Claims 84 and 86, or such other specific cause of inflammation specifically supported by the specification. **For this, it is noted that many things are noted as "associated" with something else. The Examiner is requiring the specific cause, and not some broad association. Failure to choose something specific to a specific thing (e.g., "associated with cancer" is a genera, encompassing the cancer, as well various side-effects of treatments) will yield a non-responsive notice.**

Applicant is required to choose a single specific complement inhibitor, chosen from the group consisting of SCR 13-15, Crry, (as in Claims 71-72) and a specific complement inhibitor specifically supported by the specification.

If Applicant should choose invention IV:

Applicant is required to choose a single promoter from the group consisting of Cox2L, Cox2M (as in Claim 93), or a specific promoter specifically supported in the specification.

Applicant is required to choose a single reporter from the group consisting of luciferase, GFP, RFP, hSSr2, TK, SEAP (as in Claims 95, 97-99, 101, and 104), or a specific reporter specifically supported in the specification.

If Applicant should choose invention V:

Applicant is required to choose a single promoter from the group consisting of Cox2L, Cox2M (as in Claim 108), or a specific promoter specifically supported in the specification.

Applicant is required to choose a single reporter from the group consisting of luciferase, GFP, RFP, hSSr2, TK, (as in Claims 110, 112-114, 120), or a specific reporter specifically supported in the specification.

Applicant is required to choose a single specific cause of inflammation, chosen from those of Claims 123, or such other specific cause of inflammation specifically supported by the specification. **For this, it is noted that many things are noted as "associated" with something else. The Examiner is requiring the specific cause, and not some broad association. Failure to choose something specific to a specific thing (e.g., "associated with cancer" is a genera, encompassing the cancer, as well various side-effects of treatments) will yield a non-responsive notice.**

Applicant is required to choose a single specific complement inhibitor, chosen from the group consisting of SCR 13-15, Crry, (as in Claims 71-72) and a specific complement inhibitor specifically supported by the specification.

If Applicant should choose invention VI:

Applicant is required to choose a single specific complement inhibitor, chosen from the group consisting of SCR 13-15, Crry, (as in Claims 126-127) and a specific complement inhibitor specifically supported by the specification.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

If Applicant should choose invention VII:

Applicant is required to choose a single specific complement inhibitor, chosen from the group consisting of SCR 13-15, Crry, (as in Claims 126-127) and a specific complement inhibitor specifically supported by the specification.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

The various claims which claim specific species are provided above, and within the specific invention elected, and hence, such is not required.

The following claim(s) are generic: All claims in any invention are generic to at least one species election required. Moreover, from the delineation provided above, such is inherently disclosed.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Each of the various species are known, and therefore, as each species has distinct structure, there is necessarily no special technical feature, nor is there a general inventive concept, due to the non-coextensive considerations of art and examination. Hence, it would pose a serious burden to consider any two species together, much less the combinations imposed in any specific case of permuations of groups of species.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim

will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ROBERT M. KELLY whose telephone number is (571)272-0729. The examiner can normally be reached on M-F, 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Robert M Kelly/
Primary Examiner, Art Unit 1633